

PATENT

UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Martin R. Willard et al. Confirmation No.: 8579  
Serial No.: 10/750,586 Examiner: Christopher P. Bruenjes  
Filing Date: December 29, 2003 Group Art Unit: 1772  
Docket No.: 1001.1714101 Customer No.: 28075  
For: CATHETER INCORPORATING AN IMPROVED POLYMER SHAFT

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

CERTIFICATE FOR ELECTRONIC TRANSMISSION:

The undersigned hereby certifies that this paper or papers, as described herein, are being electronically transmitted to the U.S. Patent and Trademark Office on this 10th day of April 2007.

By

  
Kathleen L. Boekley

Dear Sir:

Applicants request review of the final rejection in the above-identified application. No amendments are being filed with this Request.

This Request is being filed with a Notice of Appeal.

The review is requested for the reasons stated on the attached five sheets of arguments.

This Request is signed by an attorney or agent of record.

Respectfully submitted,

Martin R. Willard et al.

By their Attorney,

Date: April 10, 2007

/David M. Crompton/

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Attachment: Five Sheets of Pre-Appeal Brief Request Attachment

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**PRE-APPEAL CONFERENCE BRIEF**

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By

  
Kathleen L. Bookley

Dear Sir:

Appellants have carefully reviewed the Final Office Action of January 10, 2007 and the Advisory Action of March 16, 2007, in which claims 26-43 are pending, claims 26-27 have been withdrawn from consideration, and claims 28-43 have been rejected. Appellants hereby request a pre-appeal conference and file this pre-appeal conference brief concurrently with a Notice of Appeal. Favorable consideration is respectfully requested.

Claims 28-43 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Itou et al., EP 1 068 876 A2 (hereinafter "Itou") in view of Utsumi et al., U.S. Patent No. 5,258,160 (hereinafter "Utsumi"). However, all elements of these claims are not disclosed in this combination of references.

For example, claim 28 recites "a proximal portion having about 80 to about 95 weight % polyoxymethylene homogeneously blended with about 5 to about 20 weight % polyether polyester," which is not disclosed by either reference. The Examiner argues that Itou discloses homogeneous blending. Itou pertains to the manufacture of a catheter shaft by winding a first linear member around a base tube in a first direction and a second linear member around the first

linear member in a second direction, where the winding densities of the first and second linear members may be varied. The first and second linear members are melted by heating and then solidified to form a resin layer. See Figure 5, for example. The Examiner argues that Itou discloses a homogeneous blending of the two linear members in paragraph 83 where Itou states "During the heating, it is possible for the first linear member 51 and the second linear member 52 to be melted completely and to be solidified in a uniformly mixed or fused state" (hereinafter "the sentence"). Appellants can see how the sentence, if taken in isolation, may be used to support the position that the two linear members are homogeneously blended. However, the sentence was not written in isolation, and the sentence cannot, when read in context, be fairly interpreted to teach that the two linear members can be homogeneously mixed during the heating process.

Appellants want to begin by noting that reading a sentence in context is the only proper method of interpreting a text. Moreover, the rejection can only be maintained if the sentence is read in context. The sentence states that it is possible for these two linear members "to be melted completely and to be solidified in a uniformly mixed or fused state." This suggests, when read in isolation, that after the heating process, the resin layer has a completely uniform (read: homogeneous) composition where the composition of the resin layer varies neither through its thickness (as the Examiner maintains) nor along its length. (If the composition of the resin layer varied along its length, it could hardly be called "uniformly mixed.") If the composition of the resin layer does not vary along its length, it cannot anticipate any of the claims, all of which include a layer where the composition varies along its length. However, to arrive at an interpretation where the composition of the resin layer varies along its length, one has to read this sentence both in the context of other disclosure by Itou (paragraphs 54 and 55, for example) and in the knowledge generally available in the art. To be clear, Appellants are not disputing that the catheter of Itou has a composition that varies along its length; Applicants are merely saying that context matters. The context here does not support the assertion that Itou is teaching a catheter with a homogeneously blended portion.

Paragraph 83 of Itou describes two methods of heating the two linear members that result in two structurally distinguishable resin layers. The first method is described in the sentence. The second method results in a resin layer where "at least one of these linear members retains the

skeleton, that is, retains the shape before the melting to some extent in the solidified state after cooling.” “One of the [linear members], which has a lower melting point, is melted, and the other linear member having a higher melting point retains the original linear shape in part. In this case, the molten resin enters the clearance of the linear member retaining the original shape so as to be solidified.” Paragraph 83 of Itou. This second method, therefore, involves selecting materials of different melting points and melting only one of the linear members.

Applicants understand “uniformly mixed or fused state” to mean that both linear members melt around each other to form the resin layer. Think of a pizza sprinkled with shredded mozzarella cheese and shredded cheddar cheese and baked. After baking, one can still pick out the yellow bits that are the cheddar. It would be fair to say that the cheese on such a pizza is in a uniformly mixed and fused state, but it would be inaccurate to also say that the cheese is homogeneously blended.

What Itou may mean by “uniformly mixed” may merely be that both linear members are melted in the heating process and adapt their shapes to the same degree (i.e., uniformly) to produce the resin layer. This is in contrast to the second process described where the relative contribution of the linear members is non-uniform in that one of the linear members melts around the other linear member, which is not melted.

This understanding, when compared to the interpretation put forward by the Examiner, makes more sense. The heating process described in the sentence, where both linear members are melted, nicely parallels the other heating process where only one linear member is melted to flow into the clearance of the other. In contrast, if the Examiner’s interpretation of what Itou means by “solidified in a uniformly mixed or fused state” is adopted then a strange gap in the teaching of Itou emerges; Itou teaches that the heating process can be one can where the two linear members are homogeneously blended or can be one where one of the linear members is not melted at all, but Itou inexplicably does not teach a middle way where both linear members are melted or partially melted to create a non-homogeneous resin layer.

Further, the Examiner’s interpretation is inconsistent with the way the heating process is described. The two linear members are wound onto a tube and then heated, either by passing the tube through a heat die (paragraph 81) or by heating the assembly for 1 to 15 minutes. Neither process is a process that ordinarily results in homogeneous blending of two polymers. So far as

Appellants understand, one cannot rely on diffusion to homogeneously blend polymers in the time it takes to pass a tube through a heat die or even in 15 minutes; the molecules are too large. One has to mechanically agitate the polymers. Neither process includes any mechanical agitation, and therefore it is not possible for the two linear members to be homogeneously blended during the heating process as described. In contrast, it is possible for both polymers to be melted and to flow around each other.

Finally, the Examiner's interpretation is inconsistent with the rest of the specification generally. Itou, in describing a catheter of the invention (and not a manufacturing precursor), says that "the first linear member and the second linear member 52 are arranged in the form of a spiral or mesh around the outer surface of the base tube 4." Paragraph 42. Such a description is consistent with Appellants' interpretation of the sentence but is inconsistent with a catheter having homogeneously blended sections. Likewise, in the mesh embodiment of Figures 8-11, "the heating method and conditions and the molten state of the linear members are as already described." Paragraph 110. While it is possible to form a mesh using the elaborate apparatus shown in Figure 11 only to obliterate it during the heating process, it doesn't make sense to do so. Appellants' interpretation is therefore more consistent with this method as well.

The rejection is founded on the assumption that homogeneous blending as recited in the claims is inherent in Itou's teaching in the sentence. Applicants submit that here they have shown that there is another interpretation of the sentence that is not only plausible but more likely when viewed in the context of Itou's specification and the general knowledge available to one of skill in the art. Only if homogeneous blending is necessarily present in the sentence can the rejection stand. See MPEP 2112. Because homogeneous blending is not inherent (and indeed not likely) in the heating process of Itou, Itou does not teach a homogeneously blended proximal portion as recited in claim 28 or as recited in claim 29 (the two rejected independent claims). As Itou does not teach at least this element, each and every element of the claims is not taught or suggested in the cited references and a *prima facie* case of obviousness has not been made.

For at least the reasons mentioned above, all of the pending claims are allowable over the cited prior art. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,  
Martin R. Williard et al.  
By their attorney,

Date: April 10, 2007

/David M. Crompton/  
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